K031778

AUG - 7 2003

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, eRAD ImageMedical Corp., is providing a summary of safety and effectiveness information regarding the ***Practice Builder 1-2-3,*** Picture Archiving and Communications System.

1.1 Company Identification

ERAD/ ImageMedical Corp..
824 San Antonio Road
Palo Alto CA 94303
Establishment Registration: 2954766
Owner Operator Number: 9042966
Contact: Jim Connors
Tel: (650) 813-0400
Fax: (650) 813-0110

1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro CA USA 94578-1116
Tel: (510) 276-2648
Fax: (510) 276-3559
Email: regman10@attbi.com

1.3 Date of Submission
June 1, 2003

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	PracticeBuilder 1-2-3

1.5 Substantial Equivalence

PracticeBuilder 1-2-3 software is substantially equivalent to the Stentor, iSite (K013630), Stentor iVault (Class I, Exempt), Agfa IMPAX, Diagnostic Display Station (K922292) and the Ultravisual Visual PACS (Vortex) (K012097) .

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1.6 Device Description and Intended Use

PracticeBuilder 1-2-3 is a PACS system, comprised of acquisition components (GatewayServer and SendServer), a central system manager component (SmartServer), a diagnostic workstation component (Workstation and Viewer), and an archiving component (ArchiveServer). The data flow is such that patient and procedure information is optionally delivered to the central system manager, followed by the acquisition of the image objects directly from the image sources or by one of the acquisition components. After receiving the procedure information or after receiving image objects, the central system manager searches for and retrieves relevant prior procedure data from the archive component. When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information by selecting the item from the operator worklist. The image data is transmitted to and rendered on the user's workstation using the diagnostic workstation components. After using the workstation to view the images, the user optionally dictates a report into the system, after which, a user can play back the dictation and transcribe it to text. Once ***PracticeBuilder 1-2-3's*** central system manager registers a report, the report is available for access by the referring physician, or it can be exported into an information system. At some configured point in time, the image data and the report information is delivered to the archiving component for backup and long-term storage.

PracticeBuilder 1-2-3 is also a teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. ***PracticeBuilder 1-2-3*** is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

1.7 Software Development

ERAD/ImageMedical Corp., certifies that the ***PracticeBuilder 1-2-3*** software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information to the indented users.

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1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (but not supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, by non-programmers, quality control staff, and by potential customers.

Substantial Equivalence:

PracticeBuilder 1-2-3 has Indications for Use and a Target Population similar to other medical image devices, including Stentor's iSite Radiology (K013630) and Stentor's iVault (Class I Exempt), Agfa's IMPAX (K022292), and Ultravisual's Vortex (K012097). All of the functions ***PracticeBuilder 1-2-3*** performs are available in at least one of the listed substantially equivalent devices. In most cases, the function is available in all of them. There are no significant differences between ***PracticeBuilder 1-2-3*** and the collective functions of all the predicate devices. See section E for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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eRad/ImageMedical Corp.
% Mr. Gary J. Allsebrook
Official Correspondent
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578

Re: K031778
Trade/Device Name: PracticeBuilder 1-2-3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 1, 2003
Received: June 11, 2003

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031778

510(k) Number (if known): K031778

Device Name: eRAD/ImageMedical Corp., ***PracticeBuilder 1-2-3,*** Picture Archiving and Communications System

Indications For Use:

PracticeBuilder 1-2-3 is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces.

PracticeBuilder 1-2-3 is for use in hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 901.109)

David R. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031778

(Optional Format 1-2-96)